IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

EAGLE PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
	)	REDACTED - PUBLIC VERSION
v.	)	C.A. No. 18-1953-CFC
	)	
SLAYBACK PHARMA LLC,	)	[redacted]
	)	
Defendant.	)	

EAGLE PHARMACEUTICALS' OPPOSITION TO
SLAYBACK PHARMA'S MOTION FOR JUDGMENT ON THE PLEADINGS

John W. Shaw (No. 3362)
Karen E. Keller (No. 4489)
Nathan R. Hoeschen (No. 6232)
SHAW KELLER LLP
I.M. Pei Building
1105 North Market Street, 12th Floor
Wilmington, DE 19801
(302) 298-0700
jshaw@shawkeller.com
kkeller@shawkeller.com
nhoeschen@shawkeller.com
Attorneys for Eagle Pharmaceuticals, Inc.

OF COUNSEL:
Daniel G. Brown
Michelle L. Ernst
LATHAM & WATKINS LLP
885 Third Avenue
New York, NY 10022
(212) 906-1200

Kenneth G. Schuler
Marc N. Zubick
LATHAM & WATKINS LLP
330 North Wabash Avenue, Suite 2800
Chicago, IL 60611
(312) 876-7700

Dated: February 4, 2019

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES[1]

Page(s)

CASES

[1] All citations to Amiji Decl. are to the attached Declaration of Dr. Mansoor Amiji.

STATUTES

RULES

All emphases added unless indicated otherwise.

I. INTRODUCTION AND NATURE AND STAGE OF THE PROCEEDINGS

The Federal Circuit recently explained that "the purpose of a motion to dismiss is to test the sufficiency of the complaint, not to decide the merits." *Nalco Co. v. Chem-Mod, LLC*, 883 F.3d 1337, 1350 (Fed. Cir. 2018). Motions for judgment pursuant to Rule 12(c) are decided under the same standard. Remarkably, Slayback fails to cite *Nalco*, yet asks the Court to render judgment on the pleadings based on the disclosure-dedication doctrine. But disclosure-dedication can be found only where the disclosure is of "such specificity that ***one of ordinary skill in the art*** could identify the subject matter that had been disclosed and not claimed." *Pfizer, Inc. v. Teva Pharm. USA, Inc.*, 429 F.3d 1364, 1378 (Fed. Cir. 2005). The Federal Circuit explained in *Nalco* that questions over the proper interpretation of a patent's intrinsic record are "***not suitable***" and "***particularly inappropriate***" for resolution on a motion to dismiss. 883 F.3d at 1349. Consistent with that precedent, the Court should not resolve these disputes now, let alone in Slayback's favor.

Further, because disclosure-dedication is predicated on how a person of ordinary skill in the art (a "POSA") would view the specification, a defendant invoking the doctrine must satisfy an evidentiary burden. Slayback has not even attempted to do so, and its motion should be denied for that reason as well. Regardless, as a matter of both due process and fundamental fairness, a patentee should be permitted to proffer evidence of how a POSA would understand the specification before resolution on the merits. Thus, though Eagle submits that the issue is premature and that matters outside the pleadings may not be considered, out of an abundance of caution, Eagle submits the expert declaration of Dr. Mansoor Amiji, who cogently explains multiple reasons why a POSA would not view the disclosures identified by Slayback as sufficient for disclosure-dedication. Because Eagle alone has proffered evidence as to how a POSA would view the issue, Slayback's motion should be denied for this additional reason.

[redacted]

[redacted]

II. SUMMARY OF ARGUMENT

1. The Court should reject Slayback's motion because it is foreclosed in light of recent Federal Circuit authority.

2. The Court should reject Slayback's motion because Plaintiff plausibly pled infringement under the doctrine of equivalents, and Slayback does not dispute these assertions.

3. The Court should reject Slayback's motion because it fails to address how a POSA would understand the Patents-in-Suit, as required by the disclosure-dedication doctrine.

4. The Court should reject Slayback's motion because Slayback offers only unsupported attorney argument, whereas Plaintiff offers the expert opinions of Dr. Amiji who explains that Slayback's attorneys' interpretation of the specification is incorrect.

5. The Court should reject Slayback's motion because, as explained by Dr. Amiji, Slayback's disclosure-dedication argument is substantively incorrect.

6. The Court should reject Slayback's motion because Slayback's interpretation and application of the disclosure-dedication doctrine is inconsistent with Supreme Court precedent.

III. BACKGROUND AND STATEMENT OF FACTS

Plaintiff Eagle Pharmaceuticals, Inc. ("Eagle") filed this suit after Slayback provided notice that it was seeking FDA approval to sell a copycat version of Eagle's product Belrapzo®,[3] a liquid cancer medicine containing bendamustine. Eagle obtained approval for Belrapzo® in May 2018,

[2] If the Court finds the Complaint defective, Eagle respectfully requests leave to amend, which "should freely [be] give[n] when justice so requires." FED. R. CIV. P. 15(a)(2).

[3] Eagle also partners with Teva Pharmaceuticals to sell another bendamustine product, Bendeka®, which is the subject of other litigations pending before this Court, including against Slayback.

after years of research. Before Eagle developed its two novel formulations (*i.e.*, Bendeka® and Belrapzo®), bendamustine was sold in the U.S. as a lyophilized (freeze dried) powder that had to be reconstituted in water and then dissolved shortly before use in 500 ml of saline and then infused into the patient over 30-60 minutes. Belrapzo® provides a liquid product that does not need to be reconstituted and has enhanced stability. This is a significant advance for patients and health care providers because it makes bendamustine easier and safer to administer [redacted]

Eagle's Complaint pled that Slayback's NDA Product infringes four patents listed in the Orange Book and covering the formulation of Belrapzo®. U.S. Patents 9,265,831 (the "'831 Patent"); 9,572,796 (the "'796 Patent"); 9,572,797 (the "'797 Patent"); and 10,010,533 (the "'533 Patent") (the "Patents-in-Suit") list inventors Nagesh Palepu and Philip Buxton. Certain claims recite liquid bendamustine formulations having less than or equal to specified amounts of certain impurities. As discussed above, prior formulations were lyophilized because bendamustine degrades in water. (D.I. 1, Ex. A, '831 Patent at 1:31-54.) However, reconstituting the powdered drug could take 15-30 minutes and creates potential instability in the drug product prior to administration. (*Id.*) The Patents-in-Suit solve that problem by using a mixture of solvents and an antioxidant to prevent bendamustine degradation without the need for lyophilization or time-consuming, potentially destabilizing reconstitution. (*Id.* at 1:58-2:12.)

By a letter dated October 31, 2018, Slayback notified Eagle that it had filed NDA No. 212209, seeking FDA approval to market a version of Belrapzo® prior to the expiration of the Patents-in-Suit. (D.I. 1 at ¶¶ 19-21.) On December 11, 2018, Eagle filed the present case. (D.I.

1.) Slayback filed its Answer and Counterclaims on December 13, 2018, attaching excerpts of its NDA. (D.I. 8.) On January 3, Eagle filed its Answer to Slayback's Counterclaims. (D.I. 12.) The next day, Slayback filed its 12(c) motion. Neither a Rule 16(b) conference nor a Rule 26(f) conference have yet taken place or been scheduled. No discovery has taken place, despite Slayback's attaching limited documents produced in another litigation as exhibits to its motion.

IV. ARGUMENT

A. Legal Standards

Pursuant to Rule 12(c), "[a]fter the pleadings are closed—but early enough not to delay trial—a party may move for judgment on the pleadings." Fed. R. Civ. P. 12(c). Judgment on the pleadings will not be granted unless the moving party clearly establishes that no material issue of fact remains to be resolved and that the party is entitled to judgment as a matter of law. *Rosenau v. Unifund Corp.*, 539 F.3d 218, 221 (3d Cir. 2008). Because Rule 12(c) "provides for the summary disposition of a party's claims on the merits before discovery, such motions are disfavored." *Southmark Prime Plus, L.P. v. Falzone*, 776 F. Supp. 888, 891 (D. Del. 1991).

Because Slayback's motion alleges that Eagle has failed to state a claim for patent infringement, Slayback's motion is governed by the same standards that apply to a motion to dismiss made under Rule 12(b)(6). *See Rainer v. Rispoli*, No. 10-498, 2012 WL 752371, at *2 (D. Del. March 6, 2012), *quoting Spruill v. Gillis*, 372 F.3d 218, 223 n.2 (3d Cir. 2004). Such a motion may be granted only if, accepting all well-pleaded allegations in the complaint as true and viewing them in the light most favorable to the plaintiff, the court finds that under any reasonable reading of the complaint, the plaintiff is not entitled to relief. *Phillips v. Cty. of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008); *Ferrell v. Cmty. Mgmt. Servs., LLC*, No. 10-205, 2011 WL 1750452, at *1 (D. Del. May 6, 2011).

The Federal Circuit addressed the standard for motions to dismiss infringement cases in

Nalco, 883 F.3d 1337. A plaintiff "need not 'prove its case at the pleading stage.'" The Complaint need only "place the 'potential infringer . . . on notice of what activity . . . is being accused of infringement.'" *Id.* at 1350.

Infringement is a two-step inquiry: (1) the claims must be construed, and (2) the accused product must then be compared to the construed claims. *Schindler Elevator Corp. v. Otis Elevator Co.*, 593 F.3d 1275, 1281 (Fed. Cir. 2010). If an accused product does not literally infringe, it may still infringe under the doctrine of equivalents, which protects patentees from parties seeking to evade a patent by introducing "unimportant and insubstantial changes." *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 607 (1950). The filing of a § 505(b)(2) NDA is deemed a technical act of infringement. 35 U.S.C. § 271(e)(2). The acts of infringement a §505(b)(2) NDA filer has committed "include[] all of the acts that would constitute ordinary patent infringement if, upon FDA approval, the generic drug product is launched into the market." *Bristol-Myers Squibb Co. v. Mylan Pharm. Inc.*, No. 17-379, 2017 WL 3980155, at *8 (D. Del. Sept. 11, 2017).

The disclosure-dedication rule potentially places limits on the scope of equivalents if the patent in question discloses, but does not claim, alternatives to its claimed inventions. *Pfizer*, 429 F.3d at 1378. The doctrine does not apply ***any*** time a proposed equivalent appears in the specification. *PSC Comput. Prods., Inc., v. Foxconn Int'l, Inc.*, 355 F.3d 1353, 1360 (Fed. Cir. 2004). The Federal Circuit has "clarified that 'before unclaimed subject matter is deemed to have been dedicated to the public, that unclaimed subject matter must have been identified by the patentee ***as an alternative to a claim limitation***.'" *SanDisk Corp.*, 695 F.3d at 1364.

B. Slayback's Motion Should be Denied

Slayback's motion should be denied for multiple reasons.

1. Slayback's Motion Ignores Recent Federal Circuit Precedent

Far exceeding the proper inquiry in the Rule 12(c) context, Slayback improperly asks the

Court to (1) render judgment on substantive issues of infringement by selectively considering excerpted and out-of-context portions of the Patents-in-Suit and Slayback's NDA, the latter of which are not properly part of the record on this motion, and (2) asking for those documents to be interpreted in a light most favorable to ***Slayback***, rather than to Plaintiff as the law requires.

A plaintiff need not "prove its case at the pleading stage," and "the Federal Rules of Civil Procedure do not require a plaintiff to plead facts establishing that each element of an asserted claim is met." *In re Bill of Lading*, 681 F.3d 1323, 1339, 1335 (Fed. Cir. 2012). In *Nalco*, the Federal Circuit explained that a motion to dismiss was improper because it relied on claim construction and prosecution history disclaimer arguments; each of which require the Court to review the intrinsic record of the patent at issue and determine how it would be interpreted by a POSA.[4] *Compare Nalco*, 883 F.3d at 1347 ("resolution of this claim construction dispute was inappropriate at the Rule 12(b)(6) stage of the proceedings") *with Phillips v. AWH Corp.*, 415 F.3d 1303, 1332 (Fed. Cir. 2005) ("a claim should be interpreted [] from the perspective of [a POSA];"); *and compare Nalco*, 883 F.3d at 1349 ("Nalco disputes Defendants' interpretation of these reexamination statements. Resolution of that dispute, even if part of the record that can be considered, is particularly inappropriate in the Rule 12(b)(6) context.") *with Elbex Video, Ltd. v. Sensormatic Elecs. Corp.*, 508 F.3d 1366, 1371 (Fed. Cir. 2007) (prosecution history disclaimer only applies if the disclaimer is "both clear and unmistakable to [a POSA].").

[4] Claim construction and disclaimer are both ultimately questions of law. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S.Ct. 831, 837 (2015) ("When describing claim construction we concluded that it was proper to treat the ultimate question of the proper construction of the patent as a question of law...."); *iLight Techs., Inc. v. Fallon Luminous Prods. Corp.*, 375 Fed. App'x 21, 27 (Fed. Cir. 2010) ("Whether prosecution history disclaimer applies is a legal question."). But as explained in *Nalco*, these questions are inappropriate for resolution at this stage because they rely on underlying questions of fact. For this reason, Slayback's argument that disclosure-dedication (which is also a question of law) should be determined on a Rule 12(c) motion is without merit.

Slayback's disclosure-dedication argument is inappropriate for resolution at this stage for the same reasons articulated in *Nalco*. Like prosecution history disclaimer and claim construction, disclosure-dedication requires the Court to review the patent's intrinsic record and determine how it would be interpreted by a POSA, and therefore falls squarely within the *Nalco* decision. *Compare Nalco*, 883 F.3d at 1349 ("Nalco disputes Defendants' interpretation of these reexamination statements. Resolution of that dispute, even if part of the record that can be considered, is particularly inappropriate in the Rule 12(b)(6) context") *with Toro Co. v. White Consol. Indus., Inc.*, 383 F.3d 1326, 1330–31 (Fed. Cir. 2004) ("The disclosure-dedication rule limits application of the doctrine of equivalents, much in the same way as prosecution history estoppel.").[5] The Court should follow the Federal Circuit and deny Slayback's motion as premature and calling for resolution of arguments that are "particularly inappropriate" at this stage.

2. Plaintiff Plausibly Pled that Slayback Infringes the Patents-in-Suit

"Infringement, either literal or under the doctrine of equivalents, is a question of fact." *Brilliant Inst., Inc. v. GuideTech, LLC*, 707 F.3d 1342, 1344 (Fed. Cir. 2013). Eagle pled infringement under the doctrine of equivalents. (*See* D.I. 1 at ¶¶ 27-62.) Determination of equivalence is inappropriate here because it "is a determination of fact" and often centers on expert testimony. *See Graver Tank*, 339 U.S. at 609-10 ("Proof [of equivalents] can be made in any form: through testimony of experts or others versed in the technology; by documents, including texts and treatises; and, of course, by the disclosures of the prior art. Like any other issue of fact, final determination requires a balancing of credibility, persuasiveness and weight of evidence.").

Not only has Eagle alleged infringement for each Patent-in-Suit (D.I. 1 at ¶¶ 27-62), but

[5] For at least this reason, Slayback's reliance on Judge Sleet's ruling in *In re Bendamustine*, which preceded the Federal Circuit's *Nalco* decision by two years, is inappropriate and unavailing.

Eagle has also alleged numerous subsidiary facts demonstrating Slayback's infringement, [redacted] Slayback does not dispute the sufficiency of that pleading, which alone merits denial of its motion. *See Phillips*, 515 F.3d at 233 (court must take allegations in complaint to be true).

Rather than accept these factual allegations, Slayback challenges them via disclosure-dedication. (D.I. 15 at 8 ("Accordingly, because of the disclosure-dedication rule… ***Slayback's proposed 505(b)(2) product[] cannot infringe*** the claims of the patents-in-suit under the doctrine of equivalents."). Such arguments are premature (as well as incorrect). At this stage, this Court must assume the truth of Eagle's infringement allegations. *See Phillips*, 515 F.3d at 233. Further, in evaluating a Rule 12 motion, the court "draw[s] all reasonable inferences in the light most favorable to the plaintiff." *Nalco*, 883 F.3d. at 1347. Slayback's motion does ***precisely the opposite***, asking the Court to construe one isolated passage from the specification out of context, without testimony either from or pertaining to a POSA, and to draw inferences against Eagle rather than in its favor. *See* D.I. 15 at 7 [redacted] Slayback's motion is thus procedurally improper for both of the foregoing independent reasons. *See Bill of Lading*, 681 F.3d at 1346 (motions to dismiss improper where the "complaints contain detailed factual allegations and reasonable inferences drawn therefrom [] plausibly establish" infringement).

3. Slayback's Motion Improperly Relies on Incomplete Documents

Slayback's motion should also be denied because it improperly bases its argument on an incomplete portion of Slayback's NDA. The Third Circuit has emphasized that documents outside

the pleadings generally cannot form the basis of a motion to dismiss. *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997). While there is an exception if the documents are "integral" to the pleadings, Slayback's self-serving characterization of a 3-page excerpt cannot make the NDA "integral." *See* FED. R. EVID. 106.

Even if Slayback's NDA were integral, it would still be inappropriate to consider the portion Slayback relies on. Slayback asserts that its product falls within scope of the disclosure-dedication doctrine. Eagle should be allowed discovery to conduct a full infringement analysis, including product samples and development documents, as well as having its experts access Slayback's NDA. *Sunovion Pharm., Inc. v. Teva Pharm. USA, Inc.*, 731 F.3d 1271, 1279-80 (Fed. Cir. 2013) (finding biobatch data and samples relevant to infringement); *Lupin Atlantis Holdings v. Ranbaxy Labs., Ltd.*, No. 10-3897, 2011 WL 1540199, at *3 (E.D. Pa. Apr. 21, 2011) ("[A]n infringement adjudication cannot be completed merely by reviewing the ANDA, and without taking into account any other evidence—including, most notably, expert testimony."). Without this evidence, a non-infringement ruling would be premature.

The Court should not permit Slayback to block pertinent discovery, while simultaneously seeking dismissal of the complaint. Accordingly, this Court should deny Slayback's motion.

4. Slayback's Motion Fails to Address the Pertinent Standard for Evaluating Disclosure-Dedication

The Federal Circuit has explained that whether a disclosure is specific enough to trigger the disclosure-dedication doctrine is viewed through the lens of a "one of ordinary skill in the art," not a lay reader. *PSC Comput. Prods.*, 355 F.3d at 1360. Despite that requirement, Slayback offers no evidence as to how a POSA would understand the Patents-in-Suit, [redacted] As described below, Eagle vigorously disputes Slayback's attorneys' interpretation of the specification. That legitimate dispute creates a question of fact and is alone

sufficient reason to deny Slayback's motion. *Rosenau*, 539 F.3d at 221 ("Under Rule 12(c), judgment will not be granted unless the movant clearly establishes that no material issue of fact remains to be resolved and that he is entitled to judgment as a matter of law.").

Moreover, the Patents-in-Suit involve complex issues associated with pharmaceutical formulation development, which is plainly sufficiently complex so as to require expert testimony to resolve issues on the merits. *See Aspex Eyewear, Inc. v. Concepts in Optics, Inc.*, 111 Fed. App'x 582, 588 (Fed. Cir. 2004) ("This is not one of those rare cases where the invention is so simple that expert testimony is not required."); *Alexsam, Inc. v. IDT Corp.*, 715 F.3d 1336, 1347-48 (Fed. Cir. 2013) ("'[E]xpert testimony regarding matters beyond the comprehension of laypersons is sometimes essential,' particularly in cases involving complex technology."); *Outside the Box Innovations LLC v. Travel Caddy, Inc.*, 695 F.3d 1285, 1296 (Fed. Cir. 2012) ("The exclusion of a technical expert may deprive the decision-maker of knowledge and perspective relevant to the adjudication.") Courts have frequently relied upon expert testimony in evaluating disclosure-dedication. *See SanDisk Corp.*, 695 F.3d at 1362-64; *Recro Gainesville LLC v. Actavis Labs. FL, Inc.*, No. 14-1118, 2017 WL 1064883, at *5 (D. Del. Feb. 24, 2017).

Yet, Slayback's motion attaches no expert declaration explaining how a POSA would allegedly understand the disclosures of the specification of the Patents-in-Suit. Indeed, reliance on expert testimony would be improper at this preliminary stage, and it would be manifest error to credit the *ipse dixit* of Slayback's attorneys without affording Plaintiff the opportunity to fully engage in expert discovery. *See, e.g.*, *Par Pharm., Inc. v. Hospira, Inc.*, No. 17-944, 2018 WL 3343238, at *5 (D. Del. May 11, 2018) ("Given that the court does not have the benefit of expert testimony and cannot properly consider the substance of Hospira's ANDA filing at the present time, analysis under the disclosure-dedication rule is not appropriate at this stage of the

proceedings."); *In re Cyclobenzaprine*, 676 F.3d 1063, 1072 n.2 (Fed. Cir. 2012) ("expert testimony is necessary to establish" the views of a person of ordinary skill). At this stage, prior to discovery or claim construction, it is more than plausible that the specification lacks the requisite specificity and/or that the allegedly disclosed subject matter was not sufficiently identified as an alternative to trigger the disclosure-dedication rule. *See, e.g.*, *Tuna Processors, Inc. v. Haw. Int'l Seafood, Inc*., No. 05-00517, 2006 U.S. Dist. LEXIS 76885, at *14 (D. Haw. Oct. 17, 2006).

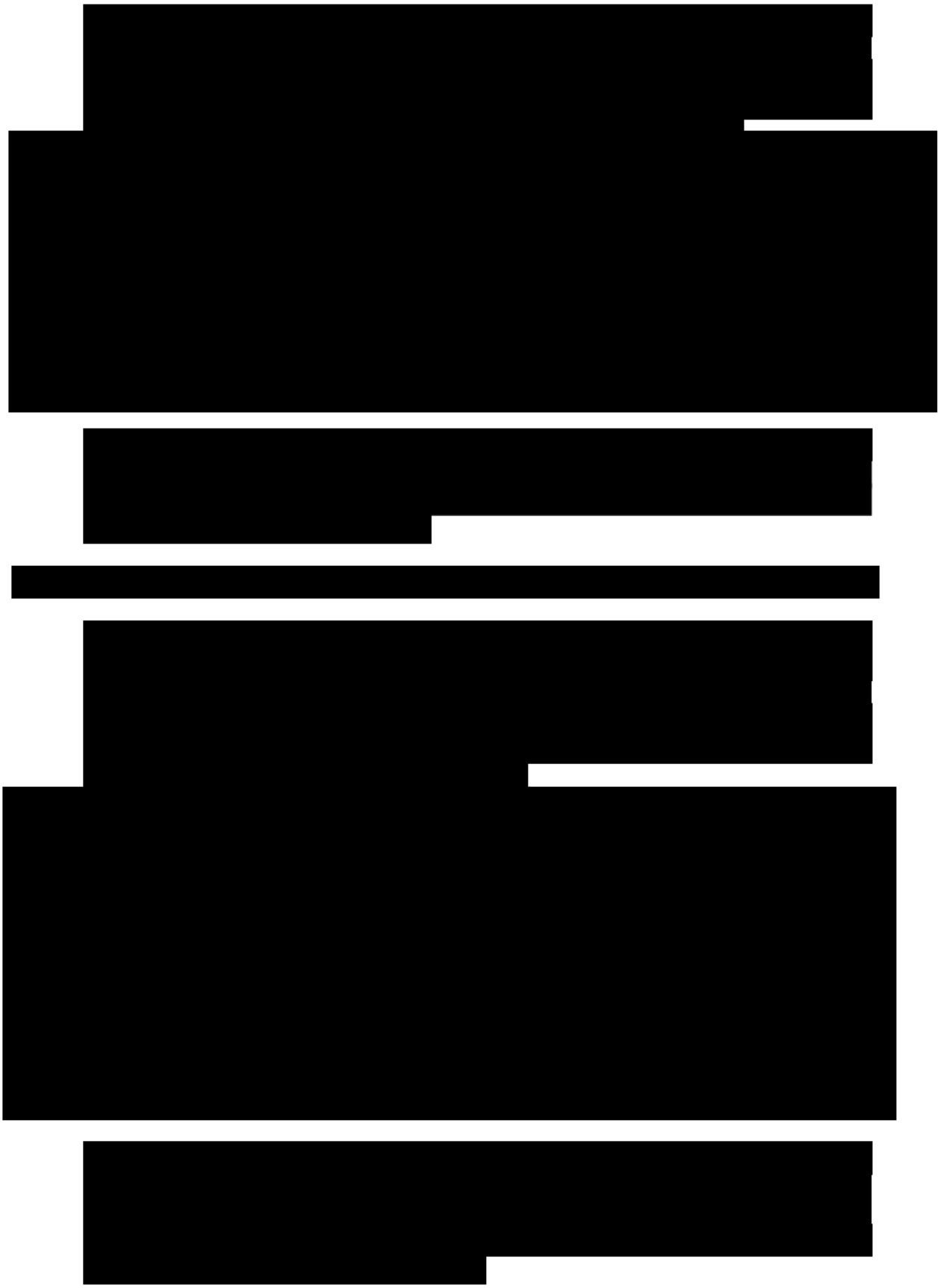
Nevertheless, should the Court seek to determine the perspective of a POSA, it should not ignore available expert testimony. At present, the only expert testimony of record is from the attached declaration of Plaintiff's expert Dr. Mansoor Amiji. As addressed more fully below, Dr. Amiji explains that Slayback's disclosure-dedication argument is deeply flawed and based on a fundamental misunderstanding of the specification of the Patents-in-Suit. (*See* Amiji Decl. at ¶¶ 23-45.) [redacted]. Given that Dr. Amiji's testimony is the only expert testimony of record, it would be improper to ignore that unrebutted expert testimony and grant Slayback's motion at this time.

5. Slayback's Argument is Substantively Incorrect

Even if the Court evaluates the substance, Slayback's motion still fails because it mischaracterizes the specification of the Patents-in-Suit. [redacted]. In order to find disclosure-dedication, the Court must determine that a POSA would understand that the unclaimed element was identified as an "alternative" to the claim limitation. *See Pfizer*, 429 F.3d at 1379. [redacted]

[redacted]

[redacted]



[redacted]

Slayback argues that "a finding of dedication does not require disclosure of a complete alternative *embodiment*, but only disclosure of an alternative to a particular claim limitation." (D.I. 15 at 7.) (emphasis in original). [redacted]

[redacted]

Slayback cites to no case where a court granted a motion to dismiss in a situation like this. Instead, it relies exclusively on *In re Bendamustine Consol. Cases*, which granted a 12(c) motion based on disclosure-dedication. (D.I. 15 at 7-8.) However, as the Court explained, that was a special case in which the patent contained a "self-explanatory" list disclosing "precise alternatives" to a single excipient, and it was "unnecessary to inquire into whether 'one of ordinary skill in the art could identify the subject matter that had been disclosed [but] not claimed.'" No. 13-2046, 2015 WL 1951399, at *2 (D. Del. April 20, 2015). [redacted]

Judge Sleet himself recognized the narrow precedential value of *In re Bendamustine*, when addressing another 12(c) motion in a different Hatch-Waxman litigation. *Amgen Inc.v. Alkem Labs., Ltd.*, No. 17-CV-815, 2017 WL 6493150 at *1 (D. Del. Dec. 19, 2017). There, Judge Sleet specifically distinguished *In re Bendamustine*, because *Amgen* involved "material disputes of fact" regarding the patent's intrinsic evidence, explaining that the presence of those factual disputes rendered the motion "frankly…premature." *Id*. at *2 n. 2. The same principle applies here. Slayback's motion requires the resolution of factual disputes regarding a POSA's understanding

of the specification. Such technical, factual disputes are not yet ripe for the Court's attention. As such, the Court should deny Slayback's premature motion.

6. Slayback's Interpretation and Application of the Disclosure-Dedication Doctrine Contradicts Supreme Court Precedent

The manner in which Slayback seeks to invoke disclosure dedication is contrary to the Supreme Court's longstanding precedent in *Graver Tank*, 339 U.S. 605. Indeed, Slayback does not cite any Supreme Court decision about the doctrine of equivalents. Instead, it urges an erroneous interpretation of the Federal Circuit's *Johnson & Johnston* decision that contradicts *Graver Tank*. But only the Supreme Court or Congress could alter that precedent, and neither has.

The claims at issue in *Graver Tank* recited in relevant part "alkaline earth metal silicate." 339 U.S. at 610. The accused product comprised ***manganese*** silicate, which was undisputedly not an alkaline earth metal. *Id.* The specification disclosed: "We have used calcium silicate and silicates of sodium, barium, iron, ***manganese***, cobalt, magnesium, nickel and aluminum, both in binary and ternary combinations, in various proportions. While a number of these are more or less efficacious in our process, ***we prefer to use silicates of alkaline earth metals*** . . . ." *Graver Tank* Petitioner's Br., 1948 WL 47309, at *58 (1948). The majority upheld the application of the DOE. 339 U.S. at 611-12. Indeed, the majority explained that it was "difficult to conceive of a case more appropriate for application of the doctrine of equivalents." *Id*. at 612.

Comparing the *Graver Tank* majority to the dissent is highly instructive and focuses Slayback's error. The dissent argued that the majority had "necessarily relie[d] on what the specifications revealed" – including "the fact that manganese is a proper substitute . . . [was] fully disclosed in the specification" – to erroneously allow the application of the DOE. 339 U.S. at 613 (Black, J., dissenting). According to the dissent, application of the DOE should have been barred because "[w]hat is not specifically claimed is dedicated to the public." *Id.* at 614. The dissent

emphasized that because the allegedly equivalent manganese silicate "was disclosed in the application and then excluded from the claims," it "therefore became public property" and should not have been within the reach of the DOE. *Id.* at 618 (Douglas, J., dissenting).

In other words, the *Graver Tank* ***dissent*** advanced a "dedication to the public" argument that is similar to Slayback's; but the ***majority*** did not, and upheld equivalent infringement. The petitioner in *Graver Tank* had argued that by disclosing in the specification that "we prefer to use silicates of the alkaline earth metals," the patentee had "thus exclude[ed] manganese which is not an alkaline earth metal silicate, but, coming to state their claims, explicitly and unambiguously *limited* the claims of the invention to . . . alkaline earth metal silicate." *Graver Tank* Petitioner's Br., 1948 WL 47309, at *59 (emphasis in original). The alleged equivalent was purportedly "thus put outside the scope of the patent," and "[n]ot having been *claimed*, even if otherwise within the discovery, it is 'presumed abandoned to the public.'" *Id.* (emphasis in original).

The majority declined to adopt any of the petitioner's or dissent's arguments. As a general matter, the Supreme Court's "reasoning . . . with respect to the disposition of [a] case is set forth in [the majority] opinion and none other." *Gill v. Whitford*, 138 S. Ct. 1916, 1931 (2018) (distinguishing majority from concurrence). That principle applies here. The *Graver Tank* majority's holding confirms that the mere fact that, even if a substitute is disclosed in the specification, there is no bar to applying the DOE.

Congress's subsequent enactment of the U.S. Patent Act of 1952, 35 U.S.C. §§ 1 *et seq.*, confirms that *Graver Tank* remains controlling law. Under § 271(a) of the statute, a patentee may bring a patent cause of action for unauthorized activities that encompass either literal infringement or infringement under the DOE. *See Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 21 (1997). Congress' use of the term "infringement" in § 271(e)(2) likewise encompasses

literal infringement and infringement under the doctrine of equivalents. That legislative action is to be understood in light of the *Graver Tank* majority's refusal to adopt the dissent's public dedication limitation on the DOE. Only an act of Congress or a later decision by the Supreme Court could alter *Graver Tank*. Yet Congress did the opposite. And subsequent Supreme Court decisions regarding the DOE reinforce *Graver Tank*.

For instance, in *Warner-Jenkinson*, the Supreme Court rejected the petitioner's argument that the DOE, as set forth in *Graver Tank*, was abrogated by the 1952 revisions to the Patent Act. Specifically, the petitioner argued that the doctrine was "inconsistent with the statutory requirement that a patentee specifically 'claim' the invention covered by a patent." *Id.* at 25. The Supreme Court explained that that same argument had been "made in *Graver Tank* in the context of the 1870 Patent Act, and failed to command a majority." *Id.* The Court emphasized that "*Graver Tank* was decided over a vigorous dissent," raising many of the same arguments the petitioner was raising in *Warner-Jenkinson*. *Id.* The Court explained that "Congress can legislate the doctrine of equivalents out of existence any time it chooses," and could "easily have responded to *Graver Tank*" in 1952 – but did not. *Id.* at 28. And in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002), the Supreme Court explained that it has repeatedly reaffirmed the DOE "over dissents that urge[] a more certain rule," including in *Graver Tank*. *Id.* at 732-33.

Congress did not enact legislation to disturb *Graver Tank*, and the Supreme Court expressly did not disturb its precedent. Slayback's attempt to rely on the Federal Circuit to argue that mere disclosure of an alleged equivalent in the specification bars the DOE is wrong as a matter of law.

V. CONCLUSION

Slayback's arguments are substantively wrong and depend on the Court improperly engaging in multiple levels of legal and factual analysis at the pleading stage. Plaintiff respectfully requests that the Court deny Slayback's motion.

Respectfully submitted,

SHAW KELLER LLP

/s/ Karen E. Keller

John W. Shaw (No. 3362)
Karen E. Keller (No. 4489)
Nathan R. Hoeschen (No. 6232)
I.M. Pei Building
1105 North Market Street, 12th Floor
Wilmington, DE 19801
(302) 298-0700
jshaw@shawkeller.com
kkeller@shawkeller.com
nhoeschen@shawkeller.com
Attorneys for Eagle Pharmaceuticals, Inc.

OF COUNSEL:
Daniel G. Brown
Michelle L. Ernst
LATHAM & WATKINS LLP
885 Third Avenue
New York, NY 10022
(212) 906-1200

Kenneth G. Schuler
Marc N. Zubick
LATHAM & WATKINS LLP
330 North Wabash Avenue, Suite 2800
Chicago, IL 60611
(312) 876-7700

Dated: February 4, 2019

CERTIFICATE OF SERVICE

I, Karen E. Keller, hereby certify that on February 4, 2019, this document was served on the persons listed below in the manner indicated:

BY EMAIL

Neal C. Belgam
Eve H. Ormerod
SMITH, KATZENSTEIN, & JENKINS LLP
1000 West Street, Suite 1501
Wilmington, DE 19801
(302) 652-8400
eormerod@skjlaw.com
nbelgam@skjlaw.com

Constance S. Huttner
Frank D. Rodriguez
James P. Barabas
Beth C. Finkelstein
BUDD LARNER, P.C.
150 John F. Kennedy Parkway
Short Hills, NJ 07078
(973) 379-4800
chuttner@buddlarner.com
frodriguez@buddlarner.com
jbarabas@buddlarner.com
bfinkelstein@buddlarner.com

/s/ Karen E. Keller
John W. Shaw (No. 3362)
Karen E. Keller (No. 4489)
Nathan R. Hoeschen (No. 6232)
SHAW KELLER LLP
I.M. Pei Building
1105 North Market Street, 12th Floor
Wilmington, DE 19801
(302) 298-0700
jshaw@shawkeller.com
kkeller@shawkeller.com
nhoeschen@shawkeller.com
Attorneys for Eagle Pharmaceuticals, Inc.